



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

March 19, 2010

MEMORANDUM:

Subject: EPA Reg. No.: 829-282/Malathion 57 EC
DP Barcode: 374820
Case No.: 0248

From: Santa K. Vinjamuri, Microbiologist
Risk Management and Implementation Branch V
Pesticide Re-evaluation Division (7508P)

To: Eric Miederhoff, CRM
Risk Management and Implementation Branch III
Pesticide Re-evaluation Division (7508P)

Applicant: Southern Agricultural Insecticides Inc.
P. O. Box 218
Palmetto FL 34220

Santa 3/19/2010
MJP

FORMULATION FROM EPA Reg. No. 829-282 LABEL:

	<u>% by wt.</u>
<u>Active Ingredient(s):</u>	
Malathion*	57.0%
<u>Inert Ingredient(s):</u>	43.0%
Total	100.0%

* Contains xylene range aromatic solvent. Contains 4.4 lbs. malathion per gallon.

BACKGROUND: In the 8 month response to the Malathion (057701) RED, the registrant is submitting acute toxicity studies to support the reregistration of their product, EPA Reg. No. 829-282. The MRID's: 430590-01 thru -06(81-1 thru 81-6) were conducted by Springborn laboratories, Inc. (SLS) Life Sciences Division. The test material used in each of these studies was Malathion 57%, EPA Reg. No.34704-108.

RECOMMENDATIONS:

- The acute toxicity studies (81-1, 81-2, 81-3, 81-4, 81-5 and 81-6) submitted are acceptable to support the reregistration of EPA Reg. No. 829-282

The acute toxicity profile for EPA Reg. No. 829-282 is currently:

Acute Oral	III	Acceptable
Acute Dermal	III	Acceptable
Acute Inhalation	IV	Acceptable
Primary Eye	III	Acceptable
Primary Dermal	IV	Acceptable
Skin Sensitization	Sensitizer	Acceptable

NOTE: The acute toxicity requirements have been satisfied for the subject product.

DATA REVIEW FOR ACUTE ORAL TOXICITY (§81-1, 870.1100)

Product Manager: Eagle/01

MRID No.: 430590-01

Reviewer: Santa K. Vinjamuri

Study Completion Date: 10/11/93

Report No.: 3225-102

Testing Facility: Springborn laboratories, Inc. (SLS) Life Sciences Division.

Author: T. N. Merriman

Quality Assurance (40 CFR §160.12): Included

Test Material: Clean Crop Malathion 57% EC

Species: Wistar albino rat

Conclusion:

1. **LD₅₀ (mg/kg):** Male: 4075 mg/kg, Female: 3754 mg/kg Combined: 3946 mg/kg

2. **Toxicity Category:** III

Classification: Acceptable

Procedure (Deviations from §81-1): none

Results:

Dose mg/kg	(number deaths/number tested)		
	Males	Females	Combined
1,500	0/5	0/5	0/10
2,500	0/5	1/5	0/10
4,000	2/5	2/5	4/10
5,000	4/5	5/5	9/10

DATA REVIEW FOR ACUTE DERMAL TOXICITY (§81-2, 870.1100)

Product Manager: Eagle/01

MRID No.: 430590-02

Reviewer: Santa K. Vinjamuri

Study Completion Date: 10/11/93

Report No.: 3225-102

Testing Facility: Springborn laboratories.,Inc. (SLS) Life Sciences Division.

Author: T. N. Merriman

Quality Assurance (40 CFR §160.12): Included

Test Material: Clean Crop Malathion 57% EC / Clear light amber liquid

Species: New Zealand White rabbits

Summary:

1. **LD₅₀ (mg/kg):** > 2000 mg/kg

2. **Toxicity Category:** III

Classification: Acceptable

Procedure (Deviations From §81-2): none

Results:

Reported Mortality

Dosage (mg/kg)	(number deaths/number tested)		
	Males	Females	Combined
2000	0/5	0/5	0/10

DATA REVIEW FOR ACUTE INHALATION TOXICITY TESTING (§81-3, 870.1300)

Product Manager: Eagle/01

MRID No.: 430590-03

Reviewer: Santa K. Vinjamuri

Study Completion Date: 10/12/93

Report No.: 3225-103

Testing Facility: Springborn laboratories.,Inc. (SLS) Life Sciences Division.

Author: R. E. Rush

Quality Assurance (40 CFR §160.12): Included

Test Material: Clean Crop Malathion 57% EC/ Clear light amber liquid

Species: Sprague-Dawley albino rat

1. **LC₅₀ (mg/L):** < 5.12 mg/L

2. **MMAD:** 0.53 µm, 0.83

GSD: ± 1.6

3. **Tox. Category:** IV

Classification: Acceptable

Procedure (Deviation From §81-3): none

Results: **Reported Mortality**

Exposure Concentration mg/L	(number deaths/number tested)		
	Males	Females	combined
5.12 mg /L	0/5	0/5	0/10

Chamber Atmosphere		
Dose Level mg /L	MMAD	GSD
5.12	2.7	±1.6

DATA REVIEW FOR PRIMARY EYE IRRITATION TESTING (§81-4, 870.2400)

Product Manager: Eagle/01
MRID No.: 430590-04

Reviewer: Santa K. Vinjamuri
Study Completion Date: 9/23/93
Report No.: 3225-104

Testing Facility: Springborn laboratories.,Inc. (SLS) Life Sciences Division.
Author: R. E. Rush

Quality Assurance (40 CFR §160.12): Included

Test Material: Clean Crop Malathion 57% EC/Clear light amber liquid

Dosage: 0.1 ml

Species: New Zealand White rabbit

Summary:

Toxicity Category: III

Classification: Acceptable

Procedure (Deviations From §81-4): none

Results:

Observations	(number "positive"/number tested)				
	Hours				Days
	1	24	48	72	7
Corneal Opacity	0/6	3/6	3/6	1/6	0/6
Iris	6/6	0/6	1/6	0/6	0/6
Conjunctivae					
Redness	6/6	4/6	0/6	0/6	0/6
Chemosis	5/6	3/6	2/6	0/6	0/6
Discharge	1/6	2/6	0/6	0/6	0/6

DATA REVIEW FOR SKIN IRRITATION TESTING (§81-5, 870.2500)

Product Manager: Eagle/01

MRID No.: 430590-05

Reviewer: Santa K. Vinjamuri

Study Completion Date: 06/18/93

Report No.: 3225-105

Testing Facility: Springborn laboratories.,Inc. (SLS) Life Sciences Division.

Author: T. N. Merriman

Quality Assurance (40 CFR §160.12): Included

Test Material: Clean Crop Malathion 57% EC/Clear light amber liquid

Dosage: 0.5 ml

Species: New Zealand White rabbit

Summary:

1. Toxicity Category: IV **PII** = .29

2. Classification: Acceptable

Procedure (Deviations From §81-5): none

Results: At 1 hr., 4/6 and at 24 hrs., 2/6 very slight erythema, all cleared by 48 hrs.

DATA REVIEW FOR DERMAL SENSITIZATION TESTING (§81-6, 870.2600)

Product Manager: Eagle/01
MRID No.: 430590-06

Reviewer: Santa K. Vinjamuri
Study Completion Date: 9/9/93
Report No.: 3225-106

Testing Facility: Springborn laboratories.,Inc. (SLS) Life Sciences Division.
Author: T. N. Merriman

Quality Assurance (40 CFR §160.12): Included

Test Material: Clean Crop Malathion 57% EC/Clear light amber liquid

Positive Control Material: 1-chloro-2-dinitrobenzene (DNCB)

Species: Albino guinea pig

Method: Buh

Summary:

1. This Product is a sensitizer

2. Classification: Acceptable

Procedure (Deviation From §81-6): None

Results:

After first induction among the test group 10/10 exhibited slight patchy erythema, which persisted in 6/10 at 48 hrs. After second and third inductions, 10/10 exhibited severe erythema with blanching, moderate edema and eschar in some animals.

Twenty four hours after challenge of previously induced guinea pigs with the test material, 3/10 moderate and 4/10 exhibited slight patchy erythema. After 48 hrs., 7/10 slight patchy erythema, and 3/10 had moderate erythema. Among the control animals 3/10 and 2/10 exhibited slight patchy erythema after 24 hrs., and 48 hrs respectively.

LABELING:

ID #: 000829-00282

MALATHION 57 EC

(Commercial Label)

INGREDIENT STATEMENT:

Contains petroleum distillates.

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wear long sleeved shirt, long pants, shoes, and socks and chemical resistant gloves ((barrier laminate, or viton, selection category G)

FIRST AID:

IF SWALLOWED: Immediately call a poison control center or doctor. Do not induce vomiting unless told to by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

USER SAFETY RECOMMENDATIONS:

User should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

User should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

Contains petroleum distillate.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

Contains petroleum distillate.

LABELING:

ID #: 000829-00282

MALATHION 57 EC
(Residential Label)

INGREDIENT STATEMENT:

Contains petroleum distillates.

SIGNAL WORD: CAUTION

HAZARDS TO HUMANS AND DOMESTIC ANIMALS:

Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

FIRST AID:

IF SWALLOWED: Immediately call a poison control center or doctor. Do not induce vomiting unless told to by a poison control center or doctor. Do not give any liquid to the person. Do not give anything by mouth to an unconscious person.

IF ON SKIN OR CLOTHING: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for treatment advice.

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.

The proposed label must contain the following guidance:

NOTE TO PHYSICIAN:

Probable mucosal damage may contraindicate the use of gastric lavage.

May pose an aspiration pneumonia hazard.

Contains petroleum distillate.